PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Ting Tina Ye et al.	Confirmation No.: 3493
Serial No.:	09/945,225	Examiner: M. DeSanto
Filing Date:	August 31, 2001	Group Art Unit: 3763
Docket No.:	1001.1471102	Customer No.: 28075
For:	MICROCATHETER WITH IMPROVED DISTAL TIP AND TRANSITIONS	

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SUPPLEMENTAL APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellants hereby submit this Supplemental Appeal Brief in furtherance of the Appeal Brief filed September 28, 2004 and in furtherance of the Notice of Appeal filed on July 28, 2004. As this is a Supplemental Appeal Brief, Appellants believe that no fees are due. However, permission is hereby granted to charge or credit deposit account number 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Mail Stop A150, Maple Grove, Minnesota 55311-1566. An assignment from the inventors, Ting Tina Ye and Gregory E. Mirigian, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 012155, Frame 0745.

II. RELATED APPEALS AND INTERFERENCES

The present application is a continuation in part of U.S. Patent Application No. 09/839,065, which is concurrently under appeal in light of similar issues and references.

III. STATUS OF CLAIMS

Claim 1 stands finally rejected under 35 U.S.C. §102(e) as being anticipated by Samson et al., U.S. Patent No. 6,090,099. Claims 1-5, 7-10, 12 and 13 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Samson et al. Claims 1-21 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Samson et al. in view of Nita et al., U.S. Patent No. 5,951,539. Appellants hereby appeal the rejection of all pending claims 1-21.

IV. STATUS OF AMENDMENTS

A Response After Final and Petition to Withdraw Finality were mailed on April 27, 2004 in response to a Final Action mailed January 28, 2004. No Advisory Action was sent or received. Appellants cannot determine whether these submissions were considered, the reasons

for continued rejection of the Application, or the basis for sustained Finality of the last Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER[1]

The invention relates to catheters or, more particularly, catheter shafts with improved designs. The inventive catheter includes a number of layers including an inner liner, a second layer, a third layer, and a fourth layer. As illustrated in Figure 4, the third layer takes the form of a coiled or braided support member such as a coiled stainless steel wire. Also as illustrated in Figure 4, the second layer has a first segment 54 ending in a distal terminus 228 and a second segment 56 extending distally from the distal terminus 228 to a radiopaque marker 40. Distal of the distal terminus 228 is a shapeable portion adapted to be thermoformed into a desired shape prior to insertion into a patient.

Turning now to the claims, claim 1 recites an intravascular catheter (Figure 1 reference number 10) comprising an elongate shaft (Figure 1, reference number 12, Figure 4, reference number 212) having a proximal end (Figure 1, reference number 14), a distal end (Figure 1, reference number 16, Figure 4 is a close view of only a distal end), and a distal tip (Figures 1, 4, reference number 20) having a shapeable length that is shapeable by thermoforming techniques (Specification, page 6, lines 11-19). The elongate shaft includes an inner liner (Figures 1, 4, reference number 24).

Claim 1 also recites that the elongate shaft includes a second layer (Figure 4, reference number 126) disposed over the inner liner, the second layer including a first segment (Figure 4, reference number 54) and a second segment (Figure 4, reference number 56), the first segment

[1] The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

extending to a distal terminus (Figure 4, reference number 228) and the second segment extending from the distal terminus to a radiopaque marker band (Figure 4, reference number 40) disposed proximal of the distal end of the shaft, wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length. Claim 1 also recites a third layer (Figure 4, reference number 30) disposed over the second layer, and a fourth layer (Figure 4, reference number 44) disposed over the third layer, the fourth layer including a proximal end and a distal end.

Claim 2, which depends from claim 1, further recites that the distal terminus is about 4 millimeters from the distal end of the shaft. (Specification, page 6, lines 11-19). Claim 3, which depends from claim 2, further recites that the shape of the distal tip can be heat set. (Specification, page 6, lines 11-19). Claim 4, which depends from claim 3, further recites that the shape of the distal tip can be heat set by steam. (Specification, page 9, line 9).

Claim 5, which depends from claim 1, further recites that the inner liner comprises polytetrafluoroethylene. (Specification, page 5, lines 14-15). Claim 6, which depends from claim 5, further recites that the second layer comprises polyether block amide. (Specification, page 6, lines 7-8). Claim 7, which depends from claim 6, further recites that the third layer comprises a coil. (Specification, page 7, lines 1-5). Claim 8, which depends from claim 7, further recites that the coil comprises stainless steel. (Specification, page 7, line 2). Claim 9, which depends from claim 7, further recites that the coil comprises nickel alloy. (Specification, page 7, line 3). Claim 10, which depends from claim 7, further recites that the coil comprises a non-ferrous metal. (Specification, page 7, lines 3-5). Claim 11, which depends from claim 7, further recites that the fourth layer comprises polyether block amide. (Specification, page 8, lines 4-5). Claim 12, which depends from claim 11, further recites that the distal end of the shaft

has an outside diameter that is less than the outside diameter of the proximal end of the shaft. (Specification, page 8, line 19, to page 9, line 2). Claim 13, which depends from claim 12, further recites that the distal end of the shaft has a durometer that is less than that of the proximal end of the shaft. (Specification, page 8, lines 16-17).

Claim 14 is an independent claim reciting an intravascular catheter (Figure 1 reference number 10) comprising an elongate shaft (Figure 1, reference number 12, Figure 4, reference number 212) having a proximal end (Figure 1, reference number 14), a distal end (Figure 1, reference number 16, Figure 4 is a close view of only a distal end), and a distal tip (Figures 1, 4, reference number 20) having a shapeable length that is shapeable by thermoforming techniques (Specification, page 6, lines 11-19). The elongate shaft includes an inner liner (Figures 1, 4, reference number 24).

Claim 14 also recites that the elongate shaft includes a second layer (Figure 4, reference number 126) disposed over the inner liner, the second layer including a first segment (Figure 4, reference number 54) and a second segment (Figure 4, reference number 56), the first segment extending to a distal terminus (Figure 4, reference number 228) and the second segment extending from the distal terminus to a radiopaque marker band (Figure 4, reference number 40) disposed proximal of the distal end of the shaft, wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length. Claim 14 also recites a third layer (Figure 4, reference number 30) disposed over the second layer, the third layer including a single coil region (Figure 4, reference 32) near the distal end of the shaft and a multiple coil region (Figure 4, reference 42) near the proximal end of the shaft. (Specification, page 7, lines 6-12). Further, claim 14 recites a fourth layer (Figure 4, reference number 44) disposed over the third layer, the fourth layer including a proximal end and a distal end, wherein

the durometer at the proximal end is greater than the durometer at the distal end. (Specification, page 8, lines 16-17).

Claim 15, which depends from claim 14, further recites that the distal terminus is about 4 millimeters from the distal end of the shaft. (Specification, page 6, lines 11-19). Claim 16, which depends from claim 15, further recites that the shape of the distal tip can be heat set. (Specification, page 6, lines 11-19). Claim 17, which depends from claim 16, further recites that the shape of the distal tip can be heat set by steam. (Specification, page 9, line 9). Claim 18, which depends from claim 14, further recites that the inner liner comprises polytetrafluoroethylene. (Specification, page 5, lines 14-15). Claim 19, which depends from claim 18, further recites that the second layer comprises polyether block amide. (Specification, page 6, lines 7-8). Claim 20, which depends from claim 19, further recites that the third layer comprises a coil. (Specification, page 7, lines 1-5). Claim 21, which depends from claim 20, further recites that the fourth layer comprises polyether block amide. (Specification, page 8, lines 4-5).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. *Whether claim 1 is unpatentable under 35 U.S.C. §102(e) for being anticipated by Samson et al., U.S. Patent No. 6,090,099.*

2. *Whether claims 1-5, 7-10, 12 and 13 are unpatentable under 35 U.S.C. §103(a) over Samson et al.*

3. *Whether claims 1-21 are unpatentable under 35 U.S.C. §103(a) over Samson et al. in view of Nita et al., U.S. Patent No. 5,951,539.*

VII. ARGUMENT

A. *Claim 1 is patentable over the §102 rejection relying on Samson et al. (U.S. Patent No. 6,090,099).*

Claim 1 recites:

> 1. An intravascular catheter, comprising:
> an elongate shaft having a proximal end, a distal end, and a distal tip having a shapable length that is shapeable by thermoforming techniques, the elongate shaft including:
> an inner liner;
> a second layer disposed over the inner liner, the second layer including a first segment and a second segment, the first segment extending to a distal terminus and the second segment extending from the distal terminus to a radiopaque marker band disposed proximal of the distal end of the shaft, wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapable length;
> a third layer disposed over the second layer; and
> a fourth layer disposed over the third layer, the fourth layer including a proximal end and a distal end.

The Examiner has asserted that "shapeable by thermoforming techniques" is a product by process claim recitation. However, the characteristic of being shapeable by thermoforming techniques would be understood by one of skill in the art as not requiring a particular process step in order to become so shapeable. Indeed, the recited element merely indicates that one of skill in the art would understand the recited catheter to be amenable to a further process, not the result of an already performed process. This is a physical characteristic of the catheter.

As defined in MPEP §2173.05(p)(I), a product by process claim "is a product claim that defines the claimed product in terms of the process by which it is made." Claim 1 does not contain language reciting how the catheter is made. Therefore claim 1 is not a product by process claim. More particularly, the recited phrase highlighted by the Examiner does not recite a process for making the claimed catheter. As such, the Examiner's refusal to consider the

claimed invention in its entirety is improper. In particular, the Examiner has not addressed whether the references cited fairly disclose a catheter that is shapeable by thermoforming techniques.

The claims recite a tip that is shapeable. The phrase "capable of" is commonly used to further describe structures in product claims, without transforming the product claims into product-by-process claims. The limitation that the tip is "shapable" means that it can be shaped, but is not necessarily shaped. This limitation describes a structural characteristic of the product, not a process step.

A process claim requires the positive recitation of method steps. For example, a process step could recite "shaping the distal tip of the catheter" or "the distal tip shaped by ..." Instead of a positively recited process step, the present claims recite characteristics of the catheter itself. The Examiner appears to be reading the phrase "shapeable by thermoforming techniques" as "shaped by thermoforming techniques," which is clearly an untenable position.

The burden of supporting a rejection under 35 U.S.C. §102 lies with the Examiner. For 35 U.S.C. §102 rejections, the reference must teach every element of the claim, as noted in MPEP §2131. The Examiner has failed to identify where in the cited reference at least one claim element is taught. Therefore, the Examiner has failed to establish a *prima facie* case of unpatentability. Instead of focusing on the claim language, the Examiner provides citation to several cases cited in the MPEP. However, none of the cited case law supports the Examiner's interpretation of the claim language.

In re Hack, 114 USPQ 161 (CCPA 1957) (Cited in MPEP §2112.02), is cited in support of the Examiner's interpretation of "shapeable" as a product-by-process limitation. The Examiner's reasons for citing this case are not clear because the case does not involve product-

by-process claims or assertions. *Hack* discusses new uses for old products, stating that patentability of a composition or machine cannot be predicated on a new use, and that only process or method claims can protect a new use. In *Hack*, the product was asserted as being patentable based on an intended use. In the present case, the claims are directed to a product with specific structural features that are not found in the cited prior art. No intended use is claimed or relied on for distinguishing the claimed invention from the prior art.

The Examiner also cites *In re Thorpe, et al.* 227 USPQ 964 (Fed. Cir. 1985) (Cited in MPEP §2113). However, the facts of *Thorpe* are quite different from the instant case. The applicant in *Thorpe* did not assert the product of its process was different from the product of the prior art, and merely argued that because the process was patentable, the resulting product should be, too. The court re-asserted the standard rule that while process claims may be allowable, the product in a product-by-process claim must be allowable based on distinguishing characteristics. The facts of the instant situation are quite different. In the instant case, Appellants do assert that their product differs structurally from the product of the prior art. Additionally, while the claims at issue in *Thorpe*, stated "product of the process of claim 1" and were thus clearly product-by-process claims, the instant claims are product claims, without reference to the process by which the product is produced.

The Examiner also cites *In re May, et al.* 197 USPQ 601 (CCPA, 1978) (Cited in MPEP §2112.02). However, the facts of *May* are also quite different from the instant case. In *May*, the applicant claimed a new use for a known drug product. The issues related to whether the effect of the drug was unexpected, not to any structural differences in products or assertions of product-by-process claims.

The recited claim element of a "shapeable length that is shapeable by thermoforming techniques" has been expressly ignored by the Examiner in contradiction to the requirements of MPEP §2131. The phrase clearly does not make recite how the catheter was formed, and is not a product by process recitation. Therefore, a *prima facie* position has not been established. Appellants do not believe that Samson et al. disclose a shapeable length that is shapeable by thermoforming techniques, and the Examiner has not even asserted such a disclosure. In light thereof, Appellants request the rejection of claim 1 be reversed.

B. *Claims 1-5, 7-10, 12 and 13 are patentable over the §103 rejections relying on Samson et al.*

1. Arguments with respect to claims 1, 2, 5, 7-10, and 13.

As described above, claim 1 recites a catheter including a shapeable length that is shapeable by thermoforming techniques, and at least this recited element is not disclosed by Samson et al. The Examiner has not cited any part of the Samson et al. reference disclosing, teaching or fairly suggesting a shapeable length that is shapeable by thermoforming techniques. Therefore, the Examiner has failed to state a *prima facie* case of unpatentability by failing to address a claim limitation. In light thereof, claim 1, as well as dependent claims 2, 5, 7-10, 12 and 13, is believed to be patentable over Samson et al.

2. Arguments with respect to claims 3 and 4.

Claims 3 and 4 rely on claim 1 as a base claim, and are subject to similar arguments as those stated with respect to claim 1. Claim 3 further recites that the shape of the distal tip can be heat set, while claim 4 further recites that the shape of the distal tip can be heat set by steam. Each of these recitations indicates properties of the material and construction of the distal tip of

the recited catheter. Therefore, even if the Examiner's position that the phrase "a shapeable length that is shapeable by thermoforming techniques" is a product by process limitation, the recited elements of claims 3 and 4 are quite clearly physical characteristics of the product, rather than the process for making a product. Further, Appellants find no indication in Samson et al., nor has the Examiner stated any reason, that these limitations could be obvious in view of Samson et al. As such, a *prima facie* case has not been stated with respect to either claim 3 or claim 4, and the rejection of these claims should be reversed.

C. *Claims 1-21 are patentable over the §103 rejections relying on Samson et al. in view of Nita et al. (U.S. Patent No. 5,951,539).*

1. *Arguments with respect to claims 1, 2, 5-15 and 18-21.*

With respect to claims 1, 2, and 5-13, Appellants note that the claim recitation that the catheter includes "a shapeable length shapeable by thermoforming techniques" has been incorrectly interpreted as creating a product-by-process limitation. Again, there is no process of making the catheter recited. The Examiner has not identified where in either reference such a product or device is disclosed. With respect to claim 1, 2 and 5-13, therefore, a *prima facie* case of unpatentability has not been established and the rejections should be reversed.

While the above is believed to be sufficient basis for overturning the standing rejections, Appellants further note that Nita et al. do not fairly suggest a shapeable length shapeable by thermoforming techniques, either. In particular, while Figures 14A-14G illustrate a number of steps taken during catheter formation to modify the cross sectional (longitudinal or axial) features of the Nita et al. catheter, Appellants do not believe that one of skill in the art would consider changes in the cross sectional characteristics of a catheter shaft as creating a shapeable

catheter. One of skill in the art would understand that a shapeable length indicates that the shape which is given is defined along the axial length of the catheter and may include, for example, a modification of cant, or inducement of curvature.

Claim 14 recites a shapeable length shapeable by thermoforming techniques, and is subject to similar analysis and arguments as stated above with respect to claim 1. In light of the above, no *prima facie* case of unpatentability has been established for claim 14 and dependent claims 15 and 18-21, and the rejections of these claims should be reversed.

2. Arguments with respect to claims 3, 4, 16 and 17.

The arguments stated above with respect to base claims 1 and 14 apply with equal weight to dependent claims 3, 4, 16 and 17. However, Appellants further note that claims 3 and 16 both recite that the shape of the distal tip of the catheter can be heat set, while claims 4 and 17 each recite that the shape of the distal tip of the catheter can be heat set by steam. These claims clearly recite physical characteristics of the respective catheters. Even if the phrase "shapeable length shapeable by thermoforming techniques" from base claims 1 and 14 is interpreted as a product by process limitation, the elements recited in claims 3, 4, 16 and 17 quite clearly cannot be understood as product by process limitations. Again, Appellants find no basis for rejecting any of these claims based on the disclosures of either Samson et al. or Nita et al., and the Examiner has stated no such basis. In particular, these thermoforming, heat set, and heat set by steam features are neither disclosed nor suggested in either reference for a completed catheter. Therefore, a *prima facie* case has not been stated, and the rejections should be overturned.

D. Conclusion.

For the reasons stated above, the rejection of claims 1-21 under 35 U.S.C. §§102(e), and 103(a) should be reversed.

Respectfully submitted,
Ting Tina Ye, et al.
By their attorney,

Date: 9/23/08

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VIII. CLAIMS APPENDIX

1. An intravascular catheter, comprising:

an elongate shaft having a proximal end, a distal end, and a distal tip having a shapable length that is shapeable by thermoforming techniques, the elongate shaft including:

an inner liner;

a second layer disposed over the inner liner, the second layer including a first segment and a second segment, the first segment extending to a distal terminus and the second segment extending from the distal terminus to a radiopaque marker band disposed proximal of the distal end of the shaft, wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapable length;

a third layer disposed over the second layer; and

a fourth layer disposed over the third layer, the fourth layer including a proximal end and a distal end.

2. The catheter in accordance with claim 1, wherein the distal terminus is about 4 millimeters from the distal end of the shaft.

3. The catheter in accordance with claim 2, wherein the shape of the distal tip can be heat set.

4. The catheter in accordance with claim 3, wherein the shape of the distal tip can be heat set by steam.

5. The catheter in accordance with claim 1, wherein the inner liner comprises polytetrafluoroethylene.

6. The catheter in accordance with claim 5, wherein the second layer comprises polyether block amide.

7. The catheter in accordance with claim 6, wherein the third layer comprises a coil.

8. The catheter in accordance with claim 7, wherein the coil comprises stainless steel.

9. The catheter in accordance with claim 7, wherein the coil comprises nickel alloy.

10. The catheter in accordance with claim 7, wherein the coil comprises a non-ferrous metal.

11. The catheter in accordance with claim 7, wherein the fourth layer comprises polyether block amide.

12. The catheter in accordance with claim 11, wherein the distal end of the shaft has an outside diameter that is less than the outside diameter of the proximal end of the shaft.

13. The catheter in accordance with claim 12, wherein the distal end of the shaft has a durometer that is less than that of the proximal end of the shaft.

14. An intravascular catheter, comprising:

an elongate shaft having a proximal end, a distal end, and a distal tip having a shapable length that is shapeable by thermoforming techniques, the elongate shaft including:

an inner liner;

a second layer disposed over the inner liner, the second layer including a first segment and a second segment, the first segment extending to a distal terminus and the second segment extending from the distal terminus to a radiopaque marker band disposed proximal of the distal end of the shaft, wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapable length;

a third layer disposed over the second layer; the third layer including a single coil region near the distal end of the shaft and a multiple coil region near the proximal end of the shaft; and

a fourth layer disposed over the third layer, the fourth layer including a proximal end and a distal end, wherein the durometer at the proximal end is greater than the durometer at the distal end.

15. The catheter in accordance with claim 14, wherein the distal terminus is about 4 millimeters from the distal end of the shaft.

16. The catheter in accordance with claim 15, wherein the shape of the distal tip can be heat set.

17. The catheter in accordance with claim 16, wherein the shape of the distal tip can be heat set by steam.

18. The catheter in accordance with claim 14, wherein the inner liner comprises polytetrafluoroethylene.

19. The catheter in accordance with claim 18, wherein the second layer comprises polyether block amide.

20. The catheter in accordance with claim 19, wherein the third layer comprises a coil.

21. The catheter in accordance with claim 20, wherein the fourth layer comprises polyether block amide.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

The related proceedings in U.S. Patent Application No. 09/839,065 are presently under appeal subject to the same timeline as the present appeal. Therefore there are no decisions to cite or provide copies of at this time.